

Maryland Board of Pharmacy

Public Board Meeting – April 18, 2001

The Public Meeting was called to order at 9:00 a.m.

ATTENDANCE:

Commissioners Present: Stanton Ades, President; W. Irving Lottier, Jr., Secretary; Commissioners: Ramona McCarthy-Hawkins; John Balch; Raymond C. Love; Wayne Dyke; Melvin Rubin; Barbara Faltz-Jackson; Jeanne Furman, Donald K. Yee; Laura Schneider and Reverend William E. Johnson, Sr.

Board Counsel; Paul Ballard, Linda Bethman

Board Staff: LaVerne G. Naesea, Executive Director; Michelle Andoll, Pharmacy Compliance Officer; Deitra Gale, Compliance Specialist; James Slade, Legislative/Regulatory Officer; Tamarra Banks, Network & Information Specialist; Sharon Demory-Cornish, Personnel Officer; Joan Lawrence, Public Education & Information Specialist; Doris Thomas, Licensing Supervisor; and Sandra A. Hines, Executive Secretary

Guest: Robert Vlk (Purdue); Catherine J. Putz and Jack Freedman (Division of Drug Control); Patricia Johnson (Dupont); Mary Kaysen (DuPont Pharmaceuticals); Kathryn Lavriha (BARR Laboratories); Howard Schiff (MPhA); Nathan Gruz (MPhA) Milton Moskowitz (PEAC); Gil Cohen (PEAC); Morris Rosenberg (PEAC)

INTRODUCTION

President Ades asked each guest to introduce him or herself.

Recusals

There were no recusals of members due to conflicts of interest

Corrections and Approval of Minutes

Page 1: fourth paragraph, correct spelling of “DuPont”

Page 7: eleventh paragraph, first sentence should be “Council of Board meeting”

Page 7: thirteenth paragraph, first sentence should be “pharmacists, pharmacies”

Ms. Faltz-Jackson moved to accept the minutes with correction amendments. Dr. Love seconded the motion, which was passed by the Board.

President/Executive Committee Report

NACDS Conference

President Ades announced that the Board has been invited to attend the 2001 NACDS Pharmacy & Technology Conference, August 18-22, 2001, at the Navy Pier Convention Center in Chicago, Illinois. The conference registration fee will be waived for state pharmacy board members and for executive directors who attend the Fourth Annual Forum. Board members will have the opportunity to attend the entire session, but would be required to attend a four or five hour issues meeting on Saturday August 18th.

President Ades announced that the State Ethics Commission would allow the Board to accept the registration fee. However, the Board cannot accept financial assistance for travel or lodging. Board members will be liable for their travel and lodging expenses. Brochures and registration forms will be available in the next couple of weeks. Any member interested in attending should send President Ades a note expressing their interest so that the Board can make arrangements.

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DHMH and Maryland Institute for Emergency Medical Services Systems (MIEMSS) Task Force on Bio-Chemical Terrorism

President Ades announced that DHMH and MIEMSS is convening a Task Force on Bio-Chemical Terrorism and is requesting assistance from the pharmacists in Maryland with developing and marshalling the plan. Initially, one or two pharmacists are needed to help develop the plan; providing expertise in handling, storage, dispensing strategies, and regulatory issues.

The Board will ask pharmacy groups in the State to nominate pharmacists who may be interested in participating on Task Force. Pharmacists who are interested in applying must submit their qualifications and indicate why they are interested. The Board will collect the information, then forward it to DHMH.

Shortage of Pharmacist Task Force

President Ades reported that the Board's legislative proposal for the Task Force did not make it through DHMH. However, based on a meeting with Dr. Benjamin, the Board will move forward with a Board initiated Task Force. Dr. Benjamin suggested that the Board invite a representative from the Department of Labor, Licensing and Regulation, the Office of Primary Care and a representative from the Maryland Health Care Commission.

The Board's initially proposed Task Force list was comprised of 16 representatives. Mr. Lottier moved that the Board accept the proposed list of representatives in addition to those submitted by Dr. Benjamin. Mr. Dyke seconded the motion, which was passed by the Board.

President Ades announced that Mr. Dyke has agreed to have the Licensing Committee oversee this Task Force. Dr. Love moved to accept this decision. Ms. McCarthy-Hawkins seconded the motion, which was passed by the Board.

Executive Director's Report

Cosmetic Contact Lenses

Ms. Naesea reported that Mr. Proctor, DHMH Chief of Staff, composed a decision memorandum to Dr. Benjamin to inform him of the reoccurring issue with the sale of cosmetic, zero powered, contact lenses by beauty supply stores in Maryland. Contact lenses, including zero powered, are classified as prescription medical devices. It is a legal violation to dispense or sell contact lenses without a valid prescription from an eye care practitioner. The FDA's position that states should handle investigations of cases involving violations, as they have direct licensing and regulatory authority over the distributors and dispensers.

Ms. Naesea reported that she participated in a conference call with Ms. Andoll, the Board of Optometry, the Board of Physician Quality Assurance, Division of Drug Control, and the Division of Food Control, to discuss the issue of which entity will monitor the distribution of non-prescribed cosmetic contact lenses. Currently, the Board of Pharmacy is the only entity that has regulatory provisions to address the issue on behalf of consumers. The other two Boards are working on regulations to address illegal dispensing of non-corrective lenses.

The Board of Pharmacy and the Board of Optometry plan to develop a joint press release through the Department of Health and Mental Hygiene (DHMH). The Board of Pharmacy and the Board of Optometry will notify licensees of the FDA rulings and the State regulations under the Board of Pharmacy. The process is in its final stage. All complaints will go through the Board of Optometry, who will refer the complaint to the Board of Pharmacy. The Board of Optometry was chosen as the contact persons, since consumers would most likely contact the Board of Optometry due to the nature of the complaint. The cases will then be referred to the Board of Pharmacy. The Board of Pharmacy will work closely with the Division of Drug Control if violators do not respond to an initial cease and desist letter.

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The American Council on Pharmaceutical Education (ACPE) Field Reviewer Training

Ms. Naesea announced that ACPE will conduct a Field Reviewer Training Workshop in conjunction with the NABP Annual Meeting, on Monday, May 7, from 1:00-3:00 p.m. at the Sheraton Seattle Hotel (Grand Ballroom). Mr. Rubin and Mr. Yee are the designated Board members to attend the Field Reviewer Training Workshop.

NABP's 97th Annual Meeting

Ms. Furman summarized the resolutions and candidates that will be voted on at the meeting.

Board of Pharmacy Strategic Planning Update

Ms. Naesea reported that the Committee is in the process of completing a final review/redraft of the Strategic Plan. The Committee's goal is to have the Plan completed and ready to start by July 1, 2001.

2002 Approved Budget

Mr. Lottier reported that the state budget analyst required that \$25,000 be cut for one of the Board's proposed new staff position in the FY 2002 budget, and that an additional \$49,474 be cut to ensure that the Board will attain its projected fund balance. In response, the Budget Committee recommended that the Board reduce \$15,641 and associated benefits for the denied position and to cut \$13,000 from the scanner maintenance contract for one year, \$12,000 from the newsletter and \$24,947 from the health education initiative. These cuts will bring the Board in conformance with the required budget cuts. The Board supported the proposed cuts.

Pharmacy School

Ms. Naesea announced that the University of Maryland Pharmacy School will hold its quarterly meeting (lecture) on Tuesday, May 1, 2001 at 8:30 a.m. Mr. David Brushwood will discuss pharmacy legislative changes and the Board will present wet lab pilot exam results. Board members interested in attending or suggesting a topic for the agenda at the meeting were asked to contact Ms. Naesea before May 1st.

HIPPA Advisory Meeting

Ms. Naesea reported that President Bush is going to immediately implement a HIPPA Portability Act. Dr. Love reported that he was invited to attend a HIPPA Advisory Meeting. Representatives from BPQA and the Managed Care Administration also participated in the discussions on how the HIPPA regulations would impact the practices regulated by each of these administrations. Dr. Love cited information from various pharmacy organization websites to describe related issues.

The HIPPA regulations were formulated under President Clinton's Administration to insure patient confidentiality. The regulations dealt with the confidential communication and transfer of information in patients' records.

President Bush's Administration was originally rumored to have viewed the regulations as being very poorly written. However, President Bush decided to go ahead with the implementation. By April 2004, all Health Care Practitioners and Organizations will have to comply with the regulations. Dr. Love announced that the State Advisory Counsel would continue to meet and get answers so that they can provide information to both providers and consumers over the next few months to give an idea of what is allowable under the HIPPA regulations.

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Board Counsel Report

Mr. Ballard gave no report at this meeting.

Legislative Officer Report

Legislative Update

Mr. Slade reported that the Board had a good Legislative Session, which is now over. He reported on the following Bills:

SB 6 entitled – Senior Prescription Drug Relief Act. The status as of April 7, 2001: Bill is in the Senate – Passed Enrolled.

SB 289 entitled – Health Care – Programs and Facilities – Pain Management. Status as of March 28, 2001: Bill is in the House – First Reading Environmental Matters. Nothing happened.

HB 418 entitled – Drugs and Prescription Records – Impounding and Disposing. Status as of April 4, 2001: bill is in the House – Passes Enrolled.

SB 686 entitled – Health Insurance Benefit Cards, Prescription Benefit Cards, or Other Technology. Status as of April 5, 2001: Bill is in the Senate – Passed Enrolled. Mr. Slade announced that President Ades testified in Annapolis, three times, on this Bill. HB 1032 entitled: Maryland Health Care Commission – User Fees. Status as of April 4, 2001: Bill is in the House – Passed Enrolled.

HB 1274 entitled: Patients' Safety Act of 2001. Status as of April 4, 2001: Bill is in the House – Returned Passed.

HB 1307 entitled: Pharmacy Errors. Status as of Marcy 7, 2001: Bill is in the House – Re-referred Environmental Matters.

HB 1032 entitled: Maryland Health Care Commission – User Fees. Status as of April 4, 2001: Bill is in the House – Passed Enrolled.

SB 772 entitled: Health Care – Therapy Management Agreements and Cooperative Procedures. Status as of April 9, 2001: Bill is in the House – Referred to the Board for an interim study.

Mr. Slade reported that Board will host a Task Force meeting in follow-up to SB 772 on Wednesday, May 2, 2001 at 12 p.m. 4201 Patterson Avenue, Room #100. Participants will include Med Chi, BPQA, Pharma, EPIC Pharmacies, Delegate Elliot, MACDS, BOP members and others. Mr. Rubin moved that the Board assign the Legislative Committee to oversee the Task Force for SB 772. Ms. Faltz-Jackson seconded the motion, which was passed by the Board.

Mr. Slade announced that the Bill signing dates are: April 20th, May 15th and May 16th. Mr. Slade will check the website to find out which Bills will be signed on each date, and notify the Board.

Regulations Update

Mr. Slade reported that the Outsourcing Regulations' comments are due by May 7, 2001.

President Ades recognized Mr. Slade for a job well done during the Legislative Session.

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Guest Presenter

There were no guest presenters at the Board meeting.

Committee Reports

Pharmacy Practice Committee

Dr. Love announced that the Practice Committee met on April 4, 2001 to discuss Medication Errors and the Collaborative Drug Therapy Management Bill. The Pharmacy Practice Committee asked the Medication Errors Task Force to be ready to prepare a report to send to the Legislature by the end of 2001. Dr. Love presented the following related Committee recommendations to the Board for approval:

- (1) The Disciplinary Committee will analyze existing sources of information, which instruct consumers on how to report concerns and initiate complaints and develop an outline of any new materials that need to be developed. This information will be forwarded to Ms. Lawrence to make recommendations to the Public Relations Committee.
- (2) The Medication Error Committee will develop an outline for the consumer on how to prevent medication error and how to report medication error and send to the Public Relations Committee.
- (3) The Public Relations Committee will be responsible for developing materials for the finished products.

Dr. Love moved that the Board accept the above recommendations as they formally appear in the Pharmacy Practice Committee Meeting Minutes of April 4, 2001. Ms. Schneider seconded the motion, which was passed by the Board.

Dr. Love reported that the Board asked the Pharmacy Practice Committee to address a question pertaining to sanitation requirements. The Committee looked at regulations from other states and concluded that the pharmacist is responsible for practicing in a hygienic manner under the Code of Conduct Regulations. However, there is no way to assure that permit holders establish and enforce policies and procedures promoting hygienic conduct by pharmacist technicians and other personnel or maintain hygienic conditions in the pharmacy without “stretching” the interpretation of existing regulations and statute.

Ms. Andoll will work with Mr. Slade to develop a rough outline on an enforceable regulation for discussion at the next Pharmacy Practice Committee meeting.

Licensing Committee

Reciprocity

Mr. Dyke presented the names of the the 15 reciprocity candidates: Mohamadou Ballo; John Bukowski; William Calhoun, Jr.; Eugene DeLara; Amani Elamin; Moheb Eslahi; James Hoang; Lina Israbian; Robert Kurowski; William McSkimming; Sandra Mitchell; Adama Sall; Maritza Santiago; Todd Stevenson and Josephine Whitford. Six candidates did not satisfy the oral competency. Three candidates will have to re-take and pass the written requirements to be approved for licensure.

Mr. Dyke motioned that all those who met the reciprocity requirements be approved for licensure. Ms. McCarthy-Hawkins seconded the motion, which was passed by the Board.

Lab Exam

Wet Lab

Mr. Rubin reported that 80 applicants have applied to take the Wet Lab Exam on June 13 and 14, 2001.

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Pilot Practical Exam

Mr. Dyke reported that the Pilot Practical Exam was administered and the results were distributed.

Ms. Schneider reported that she was responsible for grading the Pilot Practical Exam. The average score was around 80; the lowest score was 75 with the highest score being 86. The candidates consist of ten (10) Community Pharmacists; two (2) Hospital Pharmacists; one (1) Manage Care Pharmacist; one (1) Industry Pharmacist; one (1) Resident Pharmacist and one (1) Clinical Candidate.

Ms. McCarthy-Hawkins reported that she was responsible for the Test Analysis. A summary and statement of the results from the exam, were presented to the Board.

Mr. Dyke thanked Ms. Schneider and Ms. McCarthy-Hawkins for the preparation of the Test Analysis and the Board members who participated in writing the test. Mr. Dyke asked the Board to review the data and be prepared to address opinions at the next Board meeting.

Ms. McCarthy-Hawkins thanked Licensing Supervisor, Doris Thomas and all the Board staff for their assistance in the preparation of the summary.

Continuing Education Requirements – Update

Mr. Dyke reported that the Board submitted an article in the April 2001 Newsletter, and sent letters to various Pharmacies in Maryland, soliciting comments on proposed changes or considerations to the CE requirements. Thus far, the Board received four responses. The opinions varied from recommendations of no change, to favoring live CE, to no delineation to specific subject areas. The Board expects to receive more responses. Once the Board receives ample responses, the Committee will examine the data and develop recommendations to the Board.

Dr. Love reported that Delegate Hollinger announced at the HIPPA meeting that she is interested in introducing a Bill next year. The Bill would require all health professionals to annually require CE in privacy and confidentiality.

Mr. Rubin reported that Reinstatement regulations require everyone to take a law exam and meet CE requirements. Candidates who take the Reinstatement examination do not have to meet the requirements of continuing education regulations and statute. Mr. Yee motioned that the Licensing Committee accept the Reinstatement Exam as satisfying the CE requirement. Mr. Balch seconded the motion, which was passed by the Board.

Public Relations Committee

Ms. Faltz-Jackson reported that the Public Relations Committee met on March 14, 2001. The Ryan White Planning Council of the Associated Black Charities did a presentation on how pharmacists may be educated on how to work with HIV/AIDS patients. Ms. Faltz-Jackson announced the following upcoming Public Relations activities:

April 26th - Johns Hopkins University School of Nursing Health Fair will be held at the Tench Tilghman School in Baltimore

May 16th – Flower Mart at Mt. Vernon in Baltimore

May 17th – NCPIE Educate Before You Medicate Conference

June 9-12th, 2001 – Maryland Pharmacists Association Conference

The Board calendar will be placed on the Board's website by April 25th.

The Board will be generating an Annual Report for the period January 1st – June 30th 2001

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Ms. Faltz-Jackson announced that the Board now has a TV/VCR, which will be available for the Flower Mart in May. The Board will present training videos to the public at the Flower Mart.

Technology and Automation Report

Ms. Banks reported that the Board's Website now has certification information, an updated staff directory, a calendar of events and the April Newsletter is posted. The pharmacists renewal application and the Wet Lab results are now located on the Website. Persons can also now obtain the Physicians Assistance Prescriber's list and statistics on the Website.

Ms. Banks reported that the Board receives an average of 50 e-mails a month with most of the issues concerning Licensing. Technology and Automation will develop a survey with the Licensing Unit to find out the most frequently asked questions in order to provide more information through the Website.

Internet Licensing

Ms. Banks reported that NABP changed contractors and temporarily will no longer be able to provide the Board with free Internet Licensing. NABP will notify the Board of their plans to re-establish this service in the future. During the interim, the Board will solicit companies who can provide this service.

Hardware & Software Updates

Ms. Banks reported that the eight (8) laptops ordered for Board members and staff will be delivered seven (7) days after the company receives the Board's paper request.

Council of Board Report

Ms. Faltz-Jackson announced that the Council has not met since the last Board meeting.

Question for the Board

Licensing For Research and Development

Ms. Gale reported that she received a letter from Mr. Harold Boxembaum requesting permission to order quantities of medications and supplies to support his research project. The Board referred Mr. Boxembaum to the Food and Drug Administration to be registered and requested that he submit an affidavit detailing how he plans to secure prescription products, once they are in his possession. The Board will verify with the Laboratory Administration that if Mr. Boxembaum receives a permit from the Laboratory Administration, he will be able to obtain a DEA and a CDS permit.

Informational

Mr. Rubin announced to the Board that he will distribute information pertaining to the Boards and Commission In-service Training.

Mr. Rubin announced that the cost for the catered lunches during the monthly Board meetings will be \$75.00 per Board member every six (6) months. President Ades is hosting the lunch for today's Board meeting.

Ms. Schneider distributed Purdue pamphlets to the Board members and asked that they distribute the pamphlets to their stores.

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President Ades announced that the Board is celebrating Mr. Milton Moskowitz's eightieth birthday today. President Ades presented former Board member, Mr. Moskowitz the Governor's Proclamation recognizing his forty-five years of dedicated service to pharmacy practice. President Ades invited all guest in attendance to join the Board in having lunch and dessert.

Adjournment

President Ades adjourned the Public Board Meeting at 12:05 p.m.

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